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5-Year Experience With Transcatheter Transapical Mitral Valve-in-Valve Implantation for Bioprosthetic Valve Dysfunction

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Objectives The study sought to describe the authors' experience with mitral transapical transcatheter valve-in-valve implantation (TVIV).

Background Increasing numbers of mitral biological prostheses are being implanted in clinical practice. Transcatheter valve-in-valve implantation may be a lower risk alternative treatment for high-risk patients with mitral valve degeneration.

Methods Twenty-three consecutive patients with severe mitral bioprosthetic valve dysfunction underwent transapical mitral TVIV between July 2007 and September 2012. Bioprosthetic failure was secondary to stenosis in 6 (26.1%), regurgitation in 9 (39.1%), and combined in 8 (34.8%) patients.

Results All patients were elderly (mean age 81 ± 6 years) and at high-risk for conventional redo surgery (Society of Thoracic Surgeons score 12.1 ± 6.8%). Successful transapical mitral TVIV was accomplished in all patients using balloon expandable valves (Edwards Lifesciences, Irvine, California) with no intraoperative major complications. One (4.4%) major stroke and 6 (26.1%) major bleeds were reported during hospitalization. Mitral transvalvular gradient significantly decreased from 11.1 ± 4.6 mm Hg to 6.9 ± 2.2 mm Hg following the procedure ($p < 0.01$). Intervalvular mitral regurgitation was absent (47.8%) or mild (52.2%) in all cases after mitral TVIV. No cases of transvalvular regurgitation were seen. All patients were alive on 30-day follow-up. At a median follow-up of 753 days (interquartile range: 376 to 1,119 days) survival was 90.4%. One patient underwent successful mitral TVIV reintervention at 2 months due to atrial migration of the transcatheter valve. All patients alive were in New York Heart Association functional class I/II with good prosthetic valve performance.

Conclusions Transcatheter transapical mitral valve-in-valve implantation for dysfunctional biological mitral prosthesis can be performed with minimal operative morbidity and mortality and favorable midterm clinical and hemodynamic outcomes. (J Am Coll Cardiol 2013;61:1759–66) © 2013 by the American College of Cardiology Foundation

Transcatheter aortic valve replacement (TAVR) is a viable option for selected high-risk patient with aortic stenosis (1–6). Refinements in TAVR techniques and technology are anticipated to further improve clinical outcomes. The valve-in-valve procedure has emerged as clinically effective in the vast majority of patients with degenerated bioprosthetic aortic valves (7). Transcatheter mitral valve implantation therapies are being developed but will require further improvement before wide spread clinical application. Mitral transcatheter valve-in-valve (TVIV) implantation into failed mitral bioprostheses was first reported by our group in 2009, followed by several other published series confirming feasibility (8–11). Significant clinical impact can be anticipated as the absolute number of failing mitral biological prostheses continues to grow. A less invasive approach for mitral rereplacement is desirable for this ever-expanding high-risk elderly population.

We report on 23 consecutive patients with symptomatic mitral biological valve dysfunction managed successfully by mitral TVIV using Edwards SAPIEN type balloon expandable valves (Edwards Lifesciences, Irvine, California) via the apex of the left ventricle (LV).

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Abbreviations and Acronyms

IQR = interquartile range
LV = left ventricle
MVR = mitral valve replacement
NYHA = New York Heart Association
TAVR = transcatheter aortic valve replacement
TEE = transesophageal echocardiogram
TTE = transthoracic echocardiography
TVIV = transcatheter valve-in-valve

Methods

Population. From July 2007 to September 2012, 23 patients underwent transapical mitral TVIV in a single center (St. Paul's Hospital, Vancouver, Canada). All patients had previous mitral valve replacement (MVR) with biological valve prosthesis and were evaluated by a multidisciplinary heart team. The indications for reoperative MVR generally followed the American College of Cardiology/American Heart Association guidelines for mitral valve surgery (12). Patients deemed unsuitable for conventional mitral valve rereplacement were considered as potential candidates for mitral TVIV. Written informed consents were obtained from each patient. Data pertaining to baseline characteristics, procedural details and outcomes were prospectively entered into a dedicated database. Transthoracic echocardiography (TTE) and clinical follow-up were performed pre-operatively, at discharge, at 6 and 12 months, and then annually post-procedure.

Procedure. An Edwards balloon expandable valve and Ascendra transapical delivery system (Edwards Lifesciences) were used in all cases. The first-in-human mitral TVIV was performed by the implantation of a 26-mm Cribier-Edwards equine valve through a 33-F Ascendra delivery system. In all subsequent cases, the lower profile 26-F and 24-F Ascendra and Ascendra Plus delivery system were employed to deliver the bovine Edwards SAPIEN or SAPIEN XT valves (Edwards Lifesciences). Importantly, the transcatheter heart valve was crimped on the balloon of the Ascendra delivery system with the sewing cuff facing the apex of the left ventricle (the opposite way respect the transapical aortic valve implantation).

All operations were performed in a hybrid operating room equipped with standby cardiopulmonary bypass support. The technique of transapical mitral TVIV implantation was described previously (8). Briefly, patients underwent general anesthesia with single lumen intubation. A mini left anterior thoracotomy was performed at the fifth or sixth intercostal space. Hemostatic control of the LV apex was achieved by 2 octagonal pledgeted sutures. The

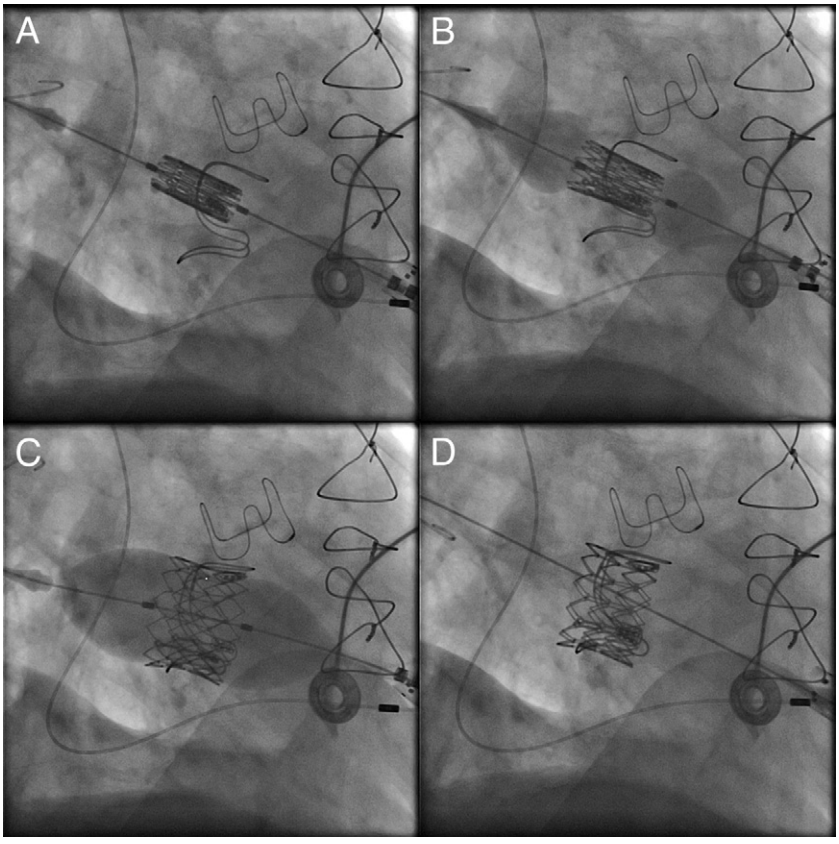

Figure 1 Step-by-Step Transapical Mitral Valve-in-Valve Procedure

Positioning **(A)** and deployment **(B to D)** of a 26-mm Edwards SAPIEN XT valve (Edwards Lifesciences) into a degenerated 27-mm Carpentier-Edwards prosthesis in mitral position.

failed mitral bioprosthesis was easily accessed with a soft J-guidewire, followed by the introduction of a 7-F sheath. A 0.035" Amplatz Extra Stiff wire (Cook Medical, Bloomington, Indiana) was exchanged by Seldinger technique, followed by the introduction of the Ascendra delivery sheath. Balloon mitral valvuloplasty of the bioprosthesis was utilized only in the first patient, but subsequently not required. Selection of an appropriately sized SAPIEN valve depended on the internal diameter of the pre-existing biological mitral prosthesis as reported by the manufacturer and by intraoperative transesophageal echocardiography. The SAPIEN valve was placed extending 3 to 5 mm atrially relatively to the mitral prosthetic sewing cuff, as guided by transesophageal echocardiogram (TEE) and fluoroscopy (Fig. 1). Cardiac motion and output was reduced by rapid ventricular pacing at a rate of 160 to 200 beats/min. TEE confirmed post-implant stability and valvular performance (Figs. 2 and 3).

Definitions and statistical analysis. Procedural success and complications were reported according to VARC-2 (Valve Academic Research Consortium) definitions (13).

Continuous variables are described as mean ± SD and median with interquartile range (IQR). Categorical variables are described by frequencies and percentages and a paired Student *t* test was employed to compare continuous variables. Survival at follow-up was calculated and presented according to the Kaplan-Meier method. All analysis was performed using the SPSS version 17.0 software (IBM, Chicago, Illinois).

Results

From July 2007 to September 2012, 23 consecutive patients underwent mitral transapical TVIV in our institution. Baseline demographics of all patients are listed in Table 1. Mean age was 81 ± 6 years and 61% of patients were female. All but 1 had New York Heart Association (NYHA) functional

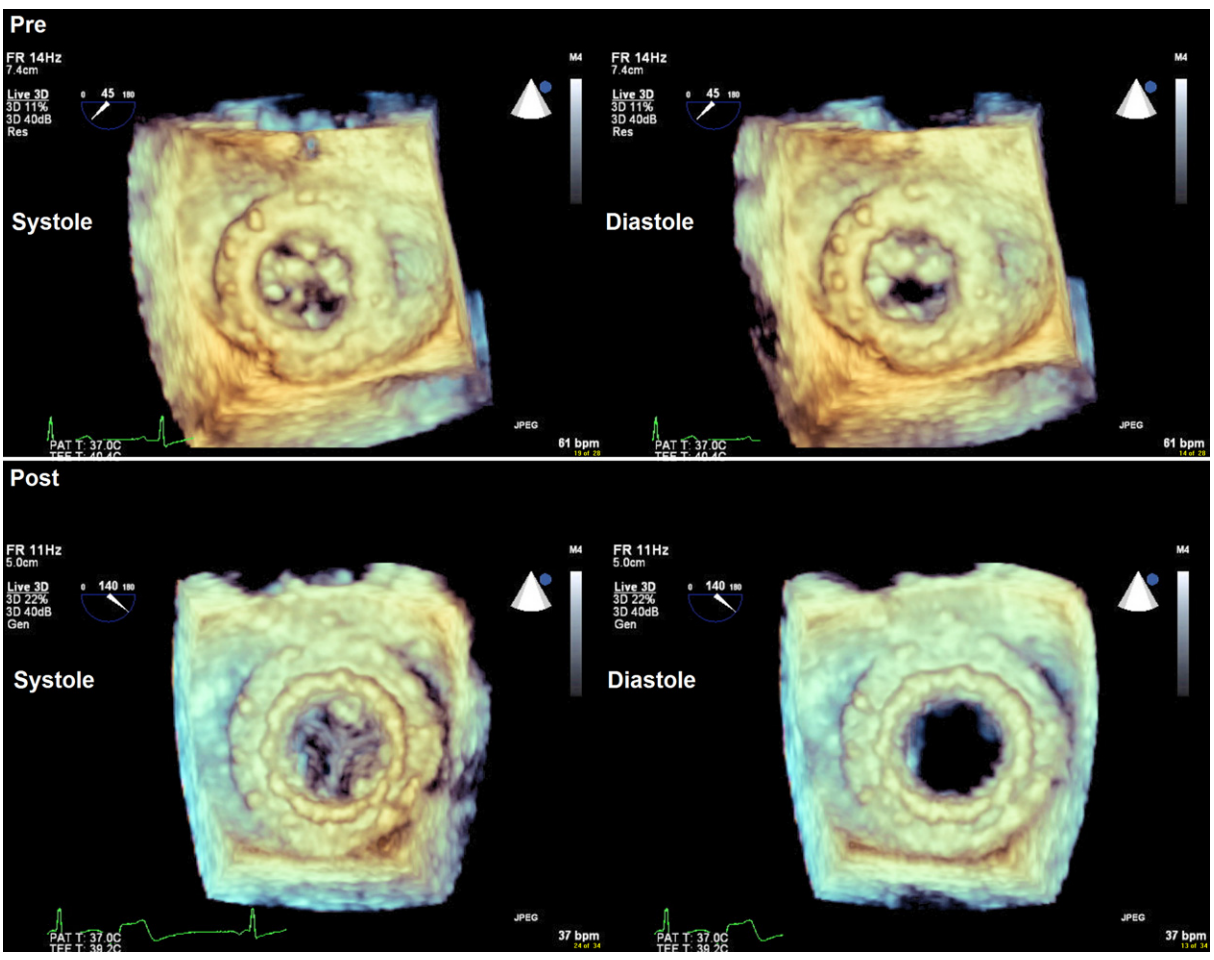

Figure 2 3D Transesophageal Echocardiogram Pre- and Post-Transapical Mitral Valve-in-Valve Implantation

Systolic and diastolic 3-D reconstruction of a degenerated 27-mm Carpentier-Edwards (Pre) (Edwards Lifesciences) and a 26-mm Edwards SAPIEN XT (Edwards Lifesciences) valve deployed inside (Post).

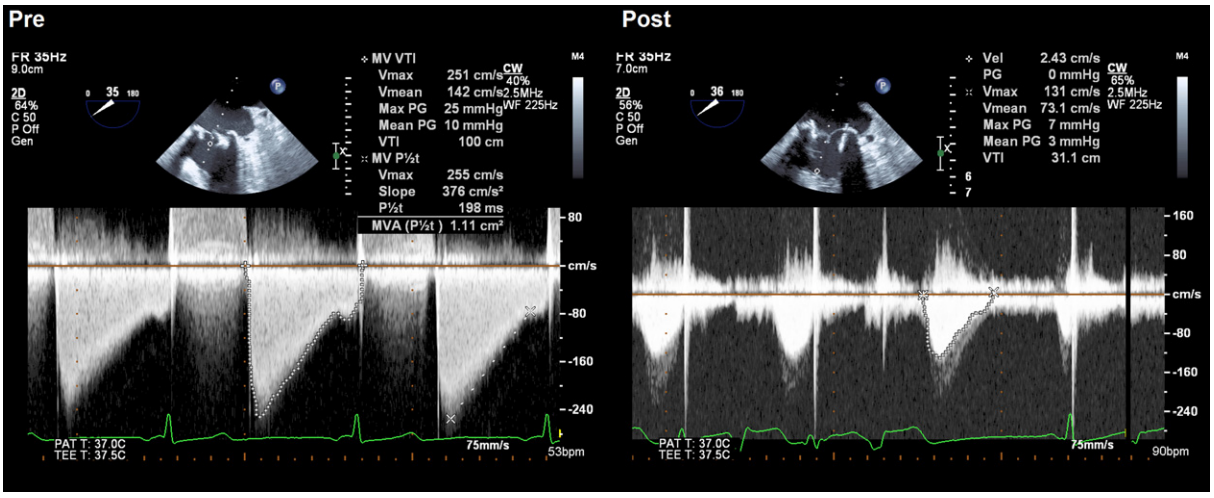

Figure 3 Doppler Continuous Transesophageal Echocardiogram

Transvalvular gradient pre- and post-transcatheter mitral valve-in-vale implantation.

class III/IV heart failure symptoms (95.7%). All patients were reviewed at multidisciplinary Transcatheter Valve Rounds and turned down for conventional reoperative MVR surgery by cardiologists and cardiac surgeons. The calculated Society of Thoracic Surgeons risk score was 12.2 ± 6.9%. The primary mechanisms of bioprosthetic failure were stenosis in 7 (30.4%), regurgitation in 9 (39.1%), and mixed in 7 (30.4%) patients. No patient had significant perivalvular regurgitation. A variety of mitral bioprosthesis were treated at a median of 10 years (IQR: 8 to 10 years) post-MVR. The manufacturer's labeled size ranged from 23 to 31 mm. Transcatheter valves implanted included the Cribier-Edwards (n = 1; 4.3%), SAPIEN (n = 12; 52.2%), and SAPIEN XT (n = 10; 43.5%) (Edwards Lifesciences). Sizes were 23 mm in 5, 26 mm in 13, and 29 mm in 5 patients. Two other patients had combined native aortic valve stenosis in addition to their mitral bioprosthetic valvular dysfunction. Both patients underwent successful combined transapical TAVR and mitral TVIV procedures. Further details of baselines characteristics of the patients are displayed in Table 2.

Table 1 Baseline Characteristics (n = 23)

Age, yrs	81.1 ± 5.8
Female	14 (60.9)
Diabetes	4 (17.4)
Peripheral vascular disease	7 (30.4)
Prior stroke/TIA	8 (34.8)
Prior CABG	10 (43.5)
Prior tricuspid intervention	4 (17.4)
COPD	6 (26.1)
CRF	13 (56.5)
Permanent AF	14 (60.9)
Prior PM	7 (30.4)
NYHA functional class III and IV	22 (95.6)
NYHA functional class II	1 (4.4)
Etiology of degeneration	
Stenosis	7 (30.4)
Regurgitation	9 (39.1)
Mixed	7 (30.4)
Echocardiogram	
Mean mitral gradient, mm Hg	11.1 ± 4.6
MVA, cm^2	1.2 ± 0.7
LVEF, %	54.5 ± 12.3
STS score, %	12.6 ± 6.9

Values are mean ± SD or n (%).

AF = Atrial fibrillation; CABG = coronary artery bypass graft surgery; COPD = chronic obstructive pulmonary disease; CRF = chronic renal failure; LVEF = left ventricular ejection fraction; MVA = mitral valve area; NYHA = New York Heart Association; PM = pacemaker; STS = Society of Thoracic Surgeons; TIA = transient ischemic attack.

Early clinical outcomes. Device success was 100% by VARC-2 definition. There were no cases of valve malpositioning or embolization. Repeat balloon dilation was successfully performed in 1 patient (4.4%) because of the presence of moderate intervalvular regurgitation without complications. No patient required mechanical circulatory support. The majority of the patients (n = 20; 86.9%) were extubated in the operating room or shortly after in the cardiac intensive care unit. Major bleeding occurred in 6 patients (26%). Reoperation for bleeding or tamponade was not required. One patient (4.4%) had an in-hospital major stroke and 2 patients (8.7%) had stage III acute kidney injury by VARC-2, 1 requiring temporary renal replacement therapy. One patient with pre-existing atrioventricular conduction disturbance required a permanent pacemaker insertion on post-operative day 3. There was no intraprocedural and no 30-day mortality. The median length of stay in hospital was 6 days (IQR: 5 to 8 days). The vast majority of patients (65.2%) were discharged on single antiplatelet therapy (aspirin 81 mg or clopidogrel 75 mg daily for

Table 2 Mitral Prosthesis Characteristics

Patients	Year Operation	Timing MVR-TVIV (yrs)	Mitral Prosthesis	Label Size External Diameter (mm)	Label Size Internal Diameter (mm)	Others Cardiac Operation	Type of Dysfunction	Type THV	Size THV (mm)
Patient #1	1990	17	Carpentier-Edwards Porcine	25	23	CABG	Stenosis	Cribier-Edwards	26
Patient #2	1997	11	Carpentier-Edwards Porcine	27	25	CABG	Regurgitation	Edwards SAPIEN	26
Patient #3	1996	13	Carpentier-Edwards Porcine	27	25	None	Regurgitation	Edwards SAPIEN	26
Patient #4	2001	8	Medtronic Mosaic	25	22.5	CABG	Stenosis	Edwards SAPIEN	23
Patient #5	2007	2	Medtronic Mosaic	25	22.5	SAVR and myomectomy	Regurgitation	Edwards SAPIEN	23
Patient #6	1999	11	Carpentier-Edwards Porcine	29	27	None	Regurgitation	Edwards SAPIEN	26
Patient #7	2001	9	Medtronic Mosaic	27	24	None	Regurgitation	Edwards SAPIEN	26
Patient #8	1999	11	Carpentier-Edwards Porcine	25	23	CABG	Stenosis	Edwards SAPIEN	23
Patient #9	2000	10	Medtronic Mosaic	23	20.5	CABG	Mixed	Edwards SAPIEN	23
Patient #10	2005	6	St Jude Medical Epic	29		TVR	Regurgitation	Edwards SAPIEN XT	26
Patient #11	2006	5	Carpentier-Edwards Perimount	29	28	CABG	Stenosis	Edwards SAPIEN XT	26
Patient #12	2004	7	Carpentier-Edwards Perimount	27	25	CABG	Mixed	Edwards SAPIEN XT	26
Patient #13	2002	9	Carpentier-Edwards Perimount	29	28	CABG and TVA	Regurgitation	Edwards SAPIEN XT	29
Patient #14	2002	8	Medtronic Mosaic	33	30	CABG and SAVR	Regurgitation	Edwards SAPIEN XT	29
Patient #15	1998	11	Medtronic Mosaic	27	24	CABG	Mixed	Edwards SAPIEN	26
Patient #16	2000	11	Medtronic Mosaic	29	26	None	Mixed	Edwards SAPIEN XT	29
Patient #17	1995	14	Carpentier-Edwards Porcine	27	25	None	Mixed	Edwards SAPIEN	26
Patient #18	1999	13	Carpentier-Edwards Perimount	23	22	TVA	Stenosis	Edwards SAPIEN XT	23
Patient #19	2001	9	Carpentier-Edwards Perimount	25	23	None	Stenosis	Edwards SAPIEN	26
Patient #20	1998	13	Carpentier-Edwards Porcine	25	23	CABG	Mixed	Edwards SAPIEN	26
Patient #21	1996	16	Carpentier-Edwards Porcine	27	25	SAVR	Regurgitation	Edwards SAPIEN XT	29
Patient #22	2003	9	Medtronic Mosaic	27	24	TVA	Stenosis	Edwards SAPIEN XT	26
Patient #23	2004	6	Carpentier-Edwards Perimount	31	29	SAVR	Mixed	Edwards SAPIEN XT	29

CABG = coronary aortic bypass grafting; MVR = mitral valve replacement; SAVR = surgical aortic valve replacement; THV = transcatheter heart valve; TVA = tricuspid valve annuloplasty; TVIV = transcatheter valve-in-valve.

6 months) and oral anticoagulation (all of these patients had baseline chronic atrial fibrillation). Seven patients (30.4%) were discharge on dual antiplatelet therapy for 6 months. One patient with atrial fibrillation considered at high risk for bleeding was discharged on warfarin alone.

Midterm clinical outcomes. Major outcomes at follow-up are listed in Table 3. At a median follow-up of 753 days (IQR: 376 to 1,119 days), Kaplan-Meier survival rate was 90.4%, with the longest follow-up of 1,448 days. The first patient suffered a periprocedural cerebrovascular event, complicated by nosocomial pneumonia and acute renal injury requiring temporary renal replacement therapy. This patient had a prolonged intensive care stay and died on post-operative day 45 with respiratory failure, despite renal and neurological recovery. One other late death occurred 135 days post-procedure from an unknown cause. An 83-year-old male patient with ischemic cardiomyopathy (LV ejection fraction 30%), had previous coronary artery bypass grafting, MVR with a 27 mm CE Perimount pericardial valve (Edwards Lifesciences) and LV aneurysmectomy (Dor) procedure in 2004, experienced a readmission due to acute heart failure 2 months after an uneventful mitral TVIV procedure with a 26-mm SAPIEN prosthesis. The transthoracic echocardiogram showed 4- to 5-mm atrial migration of the SAPIEN valve, leading to severe intervalvular regurgitation. A second transapical mitral TVIV implantation with a 29-mm

Table 3 Clinical Events, as Estimated According to Kaplan-Meier Method

	In-Hospital	Cumulative Event Rate at Last Follow-Up
All-cause death	0 (0.0)	2 (9.6)
Cardiovascular death	0 (0.0)	1 (4.5)*
Myocardial infarction	0 (0.0)	0 (0.0)
Major stroke	1 (4.4)	1 (4.4)
Minor stroke	0 (0.0)	0 (0.0)
TIA	0 (0.0)	0 (0.0)
Life-threatening bleeding	0 (0.0)	0 (0.0)
Major bleeding	6 (26.1)	6 (26.1)
Minor bleeding	0 (0.0)	0 (0.0)
Reintervention	0 (0.0)	1 (4.4)
PM implantation	1 (4.4)	1 (4.4)

Values are n (%). *Unknown death, defined as cardiovascular according to Valve Academic Research Consortium definitions.

Abbreviations as in Table 1.

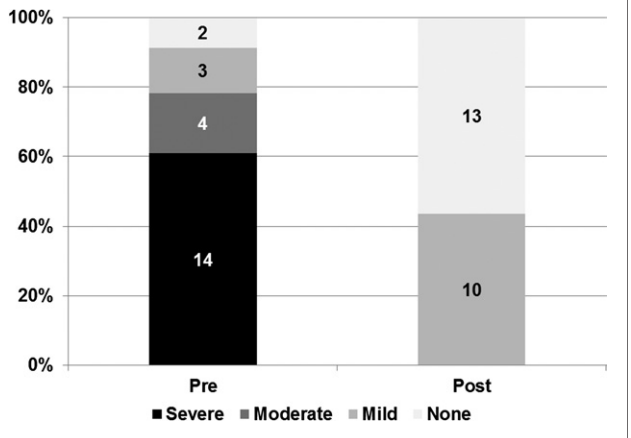

Figure 4 Mitral Regurgitation

Degree of mitral regurgitation before and after transcatheter mitral valve-in-valve implantation.

SAPIEN valve was performed without complications and no intervalvular regurgitation.

Clinical improvement in heart failure symptoms to NYHA functional class I/II were observed in all but 1 patient at last follow-up (95.6%). One patient with combined LV outflow tract obstruction from hypertrophic obstructive cardiomyopathy had persistent NYHA functional class III symptoms despite post-mitral TVIV alcohol septal ablation and good prosthetic valve function.

TVIV valvular performance. All patients were assessed by TTE prior to hospital discharge, at 6 months, 1 year, and annually after TVIV. At discharge, a significant reduction in prosthetic valvular regurgitation was seen in all patients; there was no regurgitation in 11 (47.8%) and mild transvalvular regurgitation in 12 (52.2%) (Fig. 4). The pre-operative transvalvular gradient was reduced from 11.1 ± 4.6 mm Hg to 6.9 ± 2.2 mm Hg ($p = 0.014$) (Fig. 5).

At subsequent follow-up neither structural valve deterioration nor worsening of paravalvular regurgitation was observed. In 1 patient an atrial thrombus was detected on a routine 1-month echocardiogram. This patient was asymptomatic and was subsequently treated with systemic anticoagulation with warfarin and aspirin. Complete resolution of the atrial thrombus with normal prosthetic function was confirmed at 1-year TTE (mean gradient 7.7 ± 2.6 mm Hg). No patient had moderate or severe mitral regurgitation at last follow-up.

Discussion

Transcatheter transapical mitral valve-in-valve implantation within failed biological prosthesis was initially demonstrated to be technically possible by in vitro study. Antegrade access to the mitral prosthesis can be obtained through either a direct transatrial approach, first described by Walther et al. (14) in animal study or via the venous system with transseptal access into the left atrium. We reported our initial attempts at mitral TVIV utilizing transseptal access (15) and trans-atrial access through a right thoracotomy (8). We found both approaches technically challenging, with difficulty in achieving coaxial alignment of the valve stent to the mitral prosthesis for proper valve deployment. However, conversion of the transatrial procedure to a transapical approach via a mini left thoracotomy proved successful and all subsequent cases have been performed transapically. The LV apex provides the most direct, shortest and co-axial access to the mitral valve. Procedural success was achieved in 100% of cases, without access site complications, or procedural mortality.

As the mitral valve is typically oriented toward the apex, crossing the diseased prosthesis was generally accomplished with relative ease. Fluoroscopy is most useful in cases where the prosthesis incorporates a radiopaque sewing ring; radiopaque stent posts are less helpful (Fig. 6). Fluoroscopic positioning of the implant is best accomplished in a plane perpendicular to the mitral valve, typically a 45° to 60° RAO projection. TEE is generally very helpful, and crucial when the bioprosthesis is radiolucent.

Selection of an appropriately sized implant remains controversial. We generally oversize the pre-existing prosthesis by a minimal of 10% according to the manufacturer's reported internal diameter to ensure secure anchoring of the implant within the sewing ring and minimize paravalvular regurgitation. Extreme oversizing is not desirable as a severely underexpanded implant may result in a higher transvalvular gradient, suboptimal leaflet coaptation, and

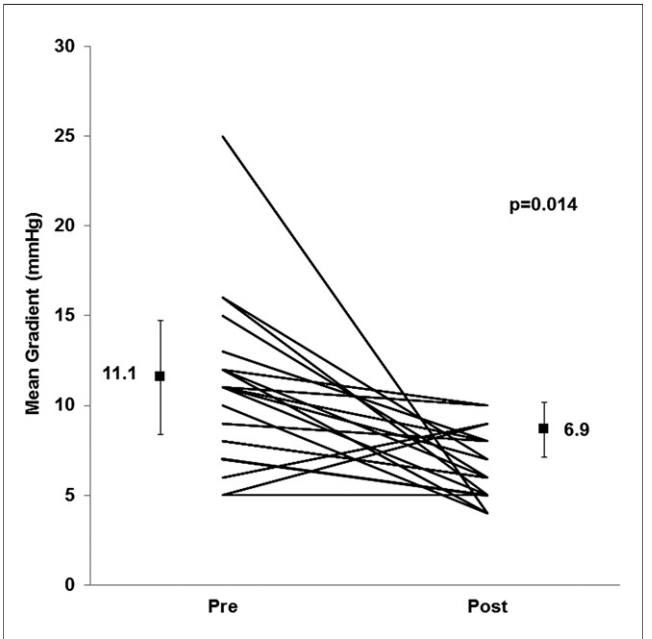

Figure 5 Transvalvular Gradient

Transvalvular gradient pre- and post-transcatheter mitral valve-in-valve implantation.

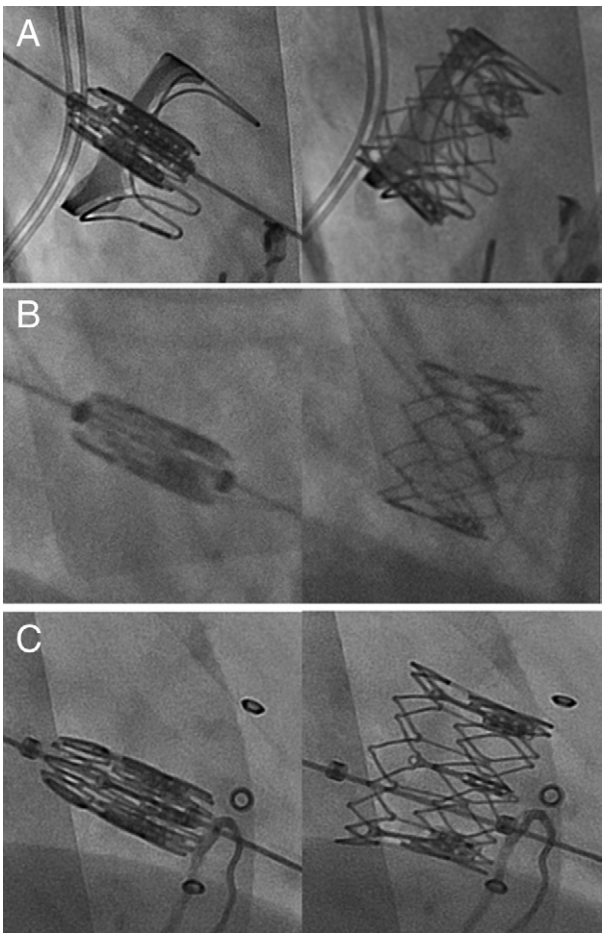

Figure 6 Mitral Bioprosthesis at Fluoroscopy

Examples of fluoroscopic appearance of 3 different mitral bioprosthetic valves **(A)** Carpentier-Edwards Porcine valve (Edwards Lifesciences); **(B)** SJM Epic tissue valve (St. Jude Medical, St. Paul, Minnesota); **(C)** Medtronic Mosaic tissue valve (Medtronic, Minneapolis, Minnesota).

compromised valve durability. In line with previous studies (9–11), in our series, the internal diameter of the previously implanted bioprosthesis provided by the manufacturers was the most important criteria for transcatheter valve sizing. Prostheses with an internal diameter less than 21.5 mm were treated with a 23-mm SAPIEN valve. A 26-mm valve was chosen for internal diameters ranging from 21.5 to 24.5 mm. Finally, for diameters larger than 24.5 mm a 29-mm valve was chosen.

Transesophageal echocardiography and multidetector computed tomography were used to confirm the internal diameter of the degenerated bioprosthesis as well as to provide further insights on bioprosthesis features (e.g., thrombi, vegetations, calcifications). However, it should be recognized that neither method has been validated in this setting.

Pre-implantation balloon valvuloplasty was performed prior to TVIV in our first patient. Subsequently this pre-dilation was avoided due to the potential risk of embolism and acute mitral regurgitation.

Study limitations. The early and midterm clinical results are encouraging with no 30-day mortality and a 1-year survival of 91% in this high-risk cohort. Significant symptomatic relief and functional improvement was observed in the majority of our patients at follow-up. The hemodynamic performance of the mitral implant was excellent with acceptable residual mean gradients of 6.8 ± 2.7 mm Hg; in line with gradients reported with surgical mitral valve bioprostheses (16), and little or no paravalvular regurgitation and durability at follow-up. Structural valve dysfunction was not seen at a median follow-up of 753 days. However, because these transcatheter valves incorporate biological tissue, as with surgical bioprosthetic valves, eventual failure can be expected. The durability of these valve stents remained unknown and will require continuing surveillance.

Conclusions

Transcatheter transapical mitral valve-in-valve implantation for dysfunctional biological mitral prosthesis can be performed with minimal morbidity and low operative mortality. Clinical and hemodynamic outcomes were favorable at short- and midterm follow-up. The transapical approach appeared particularly well suited to mitral TVIV.

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Key Words: bioprosthesis ■ mitral valve ■ transcatheter.